Rejections Under 35 U.S.C §112, first paragraph

Claims 29, 31-38, 43, 45-50 and 54

The Examiner rejected claims 29, 31-38, 43, 45-50 and 54 under 35 U.S.C. §112, first paragraph as allegedly not enabled and as allegedly failing to be supported by an appropriate written description. The Examiner stated that the claims were rejected because all of the requirements of 37 CFR §1.801-1.809 have not been met for the deposited clones referred to in the claims.

Attached hereto is a declaration by an attorney of record confirming that NRRL Deposit No. B-21416 and ATCC Accession Nos. 97880, and 97881 were deposited under the terms of the Budapest Treaty, that all restrictions upon the deposits will be irrevocably removed upon the grant of a patent on the present application, and that the deposits will be replaced if they lose viability.

In view of the forgoing, Applicant requests that the Examiner withdraw these rejections of claims 26, 31-38, 43, 45-50 and 54.

Claims 29-38

The Examiner rejected claims 29-38 under 35 U.S.C. §112, first paragraph as allegedly not enabled and as allegedly failing to be supported by an appropriate written description. The Examiner's rejection focused on claims 29, 37 and 38. These claims are drawn to polypeptides which comprise amino acids 1-844 or 850-1497 of SEQ ID NO:7. The Examiner argued that the specification does not provide an adequate written description of polypeptides comprising amino acids 1-844 or 850-1497 of SEQ ID NO:7. The Examiner also argued that the specification does not enable one skilled in the art to make and to use polypeptides comprising amino acids 1-844 or 850-1497 of SEQ ID NO:7.

As the specification explains, e.g., at pages 119 - 120, two different forms of fohy030 were identified. One form has the sequence of SEQ ID NO:7. The other form has the sequence of SEQ ID NO:9. The specification also explains that the two forms of fohy are are identical from amino acid 1 to 844 of SEQ ID NO:7 and from amino acid 850-1497 of SEQ ID NO:7. Thus, the specification clearly provides a written description of polypeptides comprising amino acids 1-844 or 850-1497 of SEQ ID NO:7.

The specification clearly contemplates polypeptides comprising either amino acids 1-844 or 850-1497 of SEQ ID NO:7 as well as polypeptides comprising the amino acid sequence of SEQ ID NO:3, 7, or 9. Such polypeptides include not only fomy030 and the two different forms of fohy030, but also longer polypeptides (e.g., fusion proteins) comprising fomy030 or fohy030 sequences. Fusion proteins are clearly taught by the specification at, for example, page 54, lines 30-32 and page 79, lines 28-32 of the specification. The disclosed invention also clearly contemplates polypeptides comprising either amino acids 1-844 or 850-1497 of SEQ ID NO:7. For example, the specification provides "equivalent differentially expressed or pathway gene product" that contain deletions or substitutions of amino acid residues encoded by differentially expressed or pathway gene products (e.g., fohy030 cDNAs) (see specification at page 52, first paragraph). Such "variant" polypeptides would include proteins comprising either amino acids 1-844 or 850-1497 of SEQ ID NO:7. The specification additionally contemplates polypeptides comprising a portion of a fohy030 or fomy030 protein (see specification at page 60, second paragraph). Those "truncated" polypeptides also would include proteins comprising either amino acids 1-844 or 850-1497 of SEQ ID NO:7. The specification provides extensive guidance for making the claimed polypeptides (see Section 5.5 at pages 51-59). The specification teaches that such polypeptides have various uses including as immunogens for producing antibodies that bind the fohy030 or fomy030 proteins and epitopes therein (see, for example, Section 5.6. at pages 59-62) and as targets for screening compounds and cellular proteins that interact with the fohy030 or fomy030 proteins (see page 52, lines 19-30 and Section 5.8 at pages 72-84). Accordingly, one skilled in the art would have known how to make and use such polypeptides with no more than routine experimentation.

In view of the forgoing, one skilled in the art clearly would have understood that the Applicant had possession of polypeptides comprising amino acids 1-844 or 850-1497 of SEQ ID NO:7. Moreover, the specification enables one skilled in the art to make and to use such polypeptides by doing no more than routine experimentation.

The Examiner's inclusion of claims 31-36 in this rejection is not understood. These dependent claims are directed to polypeptides comprising the full-length sequence of fomy030 (SEQ ID NO:3) or one of the two forms of fohy030 (SEQ ID NOs: 7 and 9). Thus, the Examiner's concerns regarding written description support and enablement for a "broad genus of

polypeptides" comprising amino acids 1-844 or 850-1497 of SEQ ID NO:7 do not appear to be relevant. Moreover, as explained above, the specification clearly contemplates the claimed polypeptides comprising the amino acid sequence of SEQ ID NO:3, 7, or 9. Such polypeptides include not only the fomy030 and fohy030 proteins but also longer protein proteins comprising an entire fomy030 or fohy030 sequence. Accordingly, one skilled in the art clearly would have understood that the Applicant had possession of such polypeptides. Moreover, the specification provides extensive guidance for producing not only the fomy030 and fohy030 protein but also longer proteins comprising a fomy030 or fohy030 sequence (see, for example, Section 5.5 at pages 51-59). The specification teaches that there are various uses for the fomy030 and fohy030 proteins as well as longer proteins comprising a fomy030 or fohy030 sequence. Such uses include as immunogens for producing antibodies that bind fomy030 and fohy030 proteins and epitopes therein (see, for example, Section 5.6. at pages 59-62) and as targets for screening compounds and cellular proteins that interact with the fomy030 and fohy030 proteins (see Section 5.8 at pages 72-84). Accordingly, one skilled in the art would have known how to make and use such polypeptides with no more than routine experimentation.

Claims 43 and 45-56

The Examiner rejected claims 43 and 45-56 as allegedly not enabled and as allegedly failing to be supported by an appropriate written description.

Written description

The rejected claims are drawn to polypeptides that consist of a specific number of amino acids and are encoded by nucleic acid molecules that hybridizes under specified conditions to a nucleic acid molecule consisting of a specified fomy030 or fohy030 nucleotide sequence. The Examiner stated that nucleic acid molecules which hybridize to a nucleic acid molecule having the sequence of SEQ ID NO:2, 6, or 8 "can include single base-paring mismatches, resulting in the alterations of the transcribed amino acid sequences." The Examiner goes on to conclude that the claims fail to meet the written description requirement because "[o]ne of skill in the relevant art would not be convinced that the inventor's had in their possession, more than SEQ ID NO:3, 7 and 9."

As the Examiner knows, an inventor need not have reduced to practice a claimed invention to show that he was "in possession" of the claimed invention so as to meet the written

description requirement. Rather, an inventor shows that he is "in possession" of the claimed invention by describing the invention using "such descriptive mean as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1574 (Fed. Cir. 1997). With respect to nucleic acid molecules, the Court of Appeals for the Federal Circuit has held that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties." *Regents of University of California v. Eli Lilly & Co.* 119 F.3d 119 1559, 1565 (Fed. Cir. 1997). By analogy, polypeptides should be capable of being similarly defined to meet the written description requirement. Here the claimed polypeptides are defined via the nucleic acid molecules encoding them. This amounts to a structural definition based on the sequence of the polypeptide, which sequence is defined by the sequence of the hybridizing nucleic acid molecule that encoded the polypeptide. Thus, it is Applicant's position that the written description requirement has been fully met for claims 43 and 45-56.

Enablement

The specification enables one skilled in the art to make and to use the polypeptides of claims 43 and 45-56. As noted above, the specification, e.g., at pages 51-59, provides extensive guidance in the making and the using of variant polypeptides. For example, a polypeptide of claim 46 can be produced by screening a library produced from melanoma cells to identify a cDNA clone which hybridizes to a nucleic acid molecule consisting of SEQ ID NO:6 under the conditions specified in the claims, identifying a clone having a open reading frame encoding a 1497 amino acid protein, and producing the encoded protein. Both cDNA library screening using fomy030 and fohy030 nucleic acid molecules and the production of polypeptides encoded by identified clones are described in the specification.

In view of the forgoing, it is Applicant's position that the specification enables one skilled in the art to make and to use the polypeptides of claims 43 and 45-56.

Conclusion

Applicant submits that all of the claims are now in condition for allowance, which action is requested. Filed herewith is a Petition for Extension of Time with the required fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 31 JAN 2001

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Appendix

29. An isolated polypeptide selected from the group consisting of:
a) a polypeptide comprising the amino acid sequence of SEQ ID NO:3;
b) a polypeptide comprising the amino acid sequence of SEQ ID NO:7;
c) a polypeptide comprising the amino acid sequence of SEQ ID NO:9;
d) a polypeptide comprising the amino acid sequence encoded by the cDNA of the clone contained in ATCC Accession No. 97880;
e) a polypeptide comprising the amino acid sequence encoded by the cDNA of the clone contained in ATCC Accession No. 97881;
f) a polypeptide comprising the amino acid sequence encoded by the cDNA of the clone contained in NRRL Deposit No. B-21416;
g) a polypeptide comprising amino acids 1 to 844 of SEQ ID NO:7; and
h) a polypeptide comprising amino acids 850 to 1497 of SEQ ID NO:7.

31. The isolated polypeptide of claim 29 wherein the polypeptide comprises the amino acid sequence of SEQ ID NO:3.

32. The isolated polypeptide of claim 29 wherein the polypeptide comprises the amino acid sequence of SEQ ID NO:7.

33. The isolated polypeptide of claim 29 wherein the polypeptide comprises the amino acid sequence of SEQ ID NO:9.

34. The isolated polypeptide of claim 29 wherein the polypeptide comprises the amino acid sequence encoded by the cDNA of the clone contained in NRRL Deposit No. B-21416.

35. The isolated polypeptide of claim 29 wherein the polypeptide comprises the amino acid sequence encoded by the cDNA of the clone contained in ATCC Accession No. 97880.

36. The isolated polypeptide of claim 29 wherein the polypeptide comprises the amino acid sequence encoded by the cDNA of the clone contained in ATCC Accession No. 97881.

37. The isolated polypeptide of claim 29 wherein the polypeptide comprises amino acids 1 to 844 of SEQ ID NO:7.

38. The isolated polypeptide of claim 29 wherein the polypeptide comprises amino acids 850 to 1497 of SEQ ID NO:7.

43. An isolated polypeptide selected from the group consisting of:

a) a polypeptide consisting of 542 amino acids and encoded by a nucleic acid molecule that hybridizes to the nucleic acid molecule of SEQ ID NO:2 or its complement at 68°C in 0.1X SSC, 0.1% SDS;

b) a polypeptide consisting of 1497 amino acids and encoded by a nucleic acid molecule that hybridizes to the nucleic acid molecule of SEQ ID NO:6 or its complement at 68°C in 0.1X SSC, 0.1% SDS;

c) a polypeptide consisting of 1533 amino acids and encoded by a nucleic acid molecule that hybridizes to the nucleic acid molecule of SEQ ID NO:8 or its complement at 68°C in 0.1X SSC, 0.1% SDS;

d) a polypeptide consisting of 542 amino acids and encoded by a nucleic acid molecule that hybridizes to a nucleic acid molecule having the sequence of the cDNA of the clone contained in NRRL Deposit No. B-21426 at 68°C in 0.1X SSC, 0.1% SDS;

e) a polypeptide consisting of 1497 amino acids and encoded by a nucleic acid molecule that hybridizes to a nucleic acid molecule having the sequence of the cDNA of the clone contained in ATCC Accession No. 97880 at 68°C in 0.1X SSC, 0.1% SDS; and

f) a polypeptide consisting of 1533 amino acids and encoded by a nucleic acid molecule that hybridizes to a nucleic acid molecule having the sequence of the cDNA of the clone contained in ATCC Accession No. 97881 at 68°C in 0.1X SSC, 0.1% SDS.

45. The isolated polypeptide of claim 43 wherein the polypeptide consists of 542 amino acids and is encoded by a nucleic acid molecule that hybridizes to the nucleic acid molecule of SEQ ID NO:2 or its complement at 68°C in 0.1X SSC, 0.1% SDS.

46. The isolated polypeptide of claim 43 wherein the polypeptide consists of 1497 amino acids and is encoded by an nucleic acid molecule that hybridizes to the nucleic acid molecule of SEQ ID NO:6 or its complement at 68°C in 0.1X SSC, 0.1% SDS.

47. The isolated polypeptide of claim 43 wherein the polypeptide consists of 1533 amino acids and is encoded by a nucleic acid molecule that hybridizes to the nucleic acid molecule of SEQ ID NO:8 or its complement at 68°C in 0.1X SSC, 0.1% SDS.

48. The isolated polypeptide of claim 43 wherein the polypeptide consists of 542 amino acids and is encoded by a nucleic acid molecule that hybridizes to a nucleic acid molecule having the sequence of the cDNA of the clone contained in NRRL Deposit No. B-21416 at 68°C in 0.1X SSC, 0.1% SDS.

49. The isolated polypeptide of claim 43 wherein the polypeptide consists of 1497 amino acids and is encoded by a nucleic acid molecule that hybridizes to a nucleic acid molecule having the sequence of the cDNA of the clone contained in ATCC Accession No. 97880 at 68°C in 0.1X SSC, 0.1% SDS.

50. The isolated polypeptide of claim 43 wherein the polypeptide consists of 1533 amino acids and is encoded by a nucleic acid molecule that hybridizes to a nucleic acid molecule

having the sequence of the cDNA of the clone contained in ATCC Accession No. 97881 at 68°C in 0.1X SSC, 0.1% SDS.

51. An isolated polypeptide encoded by a nucleic acid molecule that comprises at least 30 nucleotides and hybridizes to the nucleic acid molecule of SEQ ID NO:2 or its complement at 68°C in 0.1X SSC, 0.1% SDS.

52. An isolated polypeptide encoded by an nucleic acid molecule that comprises at least 30 nucleotides and hybridizes to the nucleic acid molecule of SEQ ID NO:6 or its complement at 68°C in 0.1X SSC, 0.1% SDS.

53. An isolated polypeptide encoded by a nucleic acid molecule that comprises at least 30 nucleotides and hybridizes to the nucleic acid molecule of SEQ ID NO:8 or its complement at 68°C in 0.1X SSC, 0.1% SDS.

54. An isolated polypeptide encoded by a nucleic acid molecule that comprises at least 30 nucleotides and hybridizes to a nucleic acid molecule having the sequence of the cDNA of the clone contained in NRRL Deposit No. B-21416 at 68°C in 0.1X SSC, 0.1% SDS.

55. An isolated polypeptide encoded by a nucleic acid molecule that comprises at least 30 nucleotides and hybridizes to a nucleic acid molecule having the sequence of the cDNA of the clone contained in ATCC Accession No. 97880 at 68°C in 0.1X SSC, 0.1% SDS.

56. An isolated polypeptide encoded by a nucleic acid molecule that comprises at least 30 nucleotides and hybridizes to a nucleic acid molecule having the sequence of the cDNA of the clone contained in ATCC Accession No. 97881 at 68°C in 0.1X SSC, 0.1% SDS.

* * *

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Andrew W. Shyjan
Serial No. : 08/862,442
Filed : May 23, 1997
Title : COMPOSITIONS AND METHODS FOR THE DIAGNOSIS, PREVENTION AND TREATMENT OF TUMOR PROGRESSION

Art Unit : 1642
Examiner : E. Canella

Commissioner for Patents
Washington, D.C. 20231

DECLARATION OF ANITA L. MEIKLEJOHN

I, Anita L. Meiklejohn, hereby declare that:

1. I am an attorney of record in the above-identified patent application.

2. Plasmids Tfohy030 and Nfohy030 described in the above-identified patent application were deposited under the terms of the Budapest Treaty with the American Type Culture Collection® (ATCC®), 10801 University Boulevard, Manassas, VA 20110-2209 on February 11, 1997 and assigned accession numbers 97880 and 97881, respectively. Plasmid fomy030 was deposited under the terms of the Budapest Treaty with the Agricultural Research Service Collection® (NRRL®), Peoria, IL on March 3, 1995 and assigned deposit number B-21416.

3. Upon granting of a patent on the above-identified patent application, all restrictions imposed by the depositor on the availability to the public of the deposited material referred to above will be irrevocably removed. Further, the deposited clones will be replaced if the depositories cannot produce viable samples.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

January 31, 2001
Date of Deposit

Carrie A. Amonte
Signature

Carrie A. Amonte
Typed or Printed Name of Person Signing Certificate

I hereby declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issued thereon.

Date: 31 JAN 2001

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